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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------------------|------------------|
| 09/803,319 | 03/09/2001 | Daniel G. Anderson | 0492611-0392 (MIT-9128) | 5731 |
| 7590 | 05/07/2003 | | | |
| Sam Pasternack Choate, Hall & Stewart 53 State Street Boston, MA 02109 | | | EXAMINER BAKER, MAURIE GARCIA | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1639 | DATE MAILED: 05/07/2003 | 17 |

Please find below and/or attached an Office communication concerning this application or proceeding.

File

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|---|--------------------------------------|---|---|
| Office Action Summary | Application No. 09/803,319 | Applicant(s) Anderson et al |  |
| | Examiner Maurie G. Baker | Art Unit 1639 | |
| <i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i> | | | |
| Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>THREE</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. | | | |
| - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | |
| Status | | | |
| 1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Feb 5, 2003</u> | | | |
| 2a) <input checked="" type="checkbox"/> This action is FINAL . 2b) <input type="checkbox"/> This action is non-final. | | | |
| 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213. | | | |
| Disposition of Claims | | | |
| 4) <input checked="" type="checkbox"/> Claim(s) <u>1-54</u> is/are pending in the application. | | | |
| 4a) Of the above, claim(s) <u>7, 13, and 21-54</u> is/are withdrawn from consideration. | | | |
| 5) <input type="checkbox"/> Claim(s) _____ is/are allowed. | | | |
| 6) <input checked="" type="checkbox"/> Claim(s) <u>1-6, 8-12, and 14-20</u> is/are rejected. | | | |
| 7) <input type="checkbox"/> Claim(s) _____ is/are objected to. | | | |
| 8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement. | | | |
| Application Papers | | | |
| 9) <input type="checkbox"/> The specification is objected to by the Examiner. | | | |
| 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | |
| 11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. | | | |
| 12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner. | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | |
| 13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. | | | |
| 14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received. | | | |
| 15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | |
| Attachment(s) | | | |
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ | |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) | |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | | 6) <input type="checkbox"/> Other: _____ | |

DETAILED ACTION

1. The Response filed February 5, 2003 (Paper No. 15) is acknowledged. Claims 1 and 2 were amended and no claims were cancelled or added. Therefore, claims 1-54 are pending.
2. Claims 7 and 13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Furthermore, claims 21-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions. Election was made without traverse in Paper No. 13. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
3. Therefore, claims 1-6, 8-12 and 14-20 are under examination.

Status of Rejections

4. The previous rejection under 35 U.S.C. 102(b) over Schreiber et al is withdrawn in view of applicant's claim amendments. Also, the rejection of claims 12 and 14 under 35 U.S.C. 112, first paragraph for enablement is withdrawn in view of applicant's arguments. All other rejections are maintained. Applicant's arguments are addressed following each rejection. Also, new rejections have been made as necessitated by applicants amendments.

Maintained Rejections
Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-6, 8-12 and 14-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. Applicant's claims are directed to a "microarray of polymeric biomaterials". The claimed microarray also comprises "a base comprising a cytophobic surface" and "a plurality of discrete polymeric biomaterial elements". The claims use generic terminology such as "polymeric biomaterials", "base" and "cytophobic surface". These terms could encompass an enormous variety of different entities.

The language of the specification should describe the claimed invention so that one skilled in the art can recognize what is claimed. A description of a compound in terms of its function fails to distinguish the compound from others having the same activity or function. A description of what a material does, rather than of what it is,

usually does not suffice. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *University of California v. Eli Lilly and Co.* (U.S. Court of Appeals Federal Circuit (CAFC) 43 USPQ2d 1398 7/22/1997 Decided July 22, 1997; No. 96-1175).

The specification discloses only extremely limited examples of the preparation and use of such a “microarray”. These products are made up of pieces (i.e. “polymeric biomaterials”, “base” and “cytophobic surface”) that could encompass very different moieties such as various inorganic and organic molecules. Applicant’s claimed scope represents only an invitation to experiment regarding possible “polymeric biomaterials”, “base” materials and “cytophobic surface[s]”. The disclosure is neither representative of the claimed genus, nor does it represent a substantial portion of the claimed genus. Moreover, the claimed genus encompasses members which are yet to be prepared or envisioned. This further evidences that instant disclosure does not constitute support for the claimed genus or a substantial portion thereof.

Response to Arguments

7. Applicant's arguments filed February 5, 2003 have been fully considered but are not found persuasive. The examiner's rationale is set forth below.

8. Applicant argues that the instant claims are adequately described (Response, pages 3-4) and states that “the present specification clearly puts the public on notice that, at the time of

filling, Applicant had invented a broadly applicable method for preparing microarrays". However, the instant claims are drawn to microarrays *per se*, and not to methods of making.

9. As stated above, applicant's claims are directed to a "microarray of polymeric biomaterials". The claimed microarray also comprises "a base comprising a cytophobic surface" and "a plurality of discrete polymeric biomaterial elements". The claims use generic terminology such as "polymeric biomaterials", "base" and "cytophobic surface". These terms could encompass an enormous variety of different entities and thus could encompass an infinite number of variations. Note that "the essential goal of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977), cert. denied, 434 U.S. 1064 (1978). Another objective is to put the public in possession of what the applicant claims as the invention so that the public may ascertain if the patent applicant claims anything that is in common use, or already known. *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356 (1822).

10. Also noted is the need for representative examples in an unpredictable art that are necessary to demonstrate that applicant had possession of the full scope of the claimed invention. See *In re Riat* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr* (CCPA 1971) 444 F 2d 349, 151 USPQ 724 (for enablement) and *University of California v. Eli Lilly and Co* cited above (for disclosure); all cited above. The more unpredictable the art the greater the showing required (e.g. by "representative examples") for both enablement and adequate disclosure. Applicant's

specification discloses only *extremely limited examples* of the preparation and use of such a “microarray”.

11. A representative number of species means that the species that are adequately described are representative of the entire genus. When there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. Therefore it is deemed that the instant specification lacks adequate support relating to the genus of the claimed microarrays (and their constituents) as there is not a description of a sufficient variety of species to reflect the variation within the genus. For these reasons, the above rejection under 35 U.S.C. 112, first paragraph is maintained.

Maintained Rejections
Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites “drugs”, “growth factors”, “combinatorial compounds” and “adducts thereof, and mixtures thereof” in the Markush group. It is unclear what would or would not comprise each of the above members or “adducts thereof, and mixtures thereof”. The specification does not provide a standard for ascertaining such terms, and

thus one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Response to Arguments

14. Applicant's arguments filed February 5, 2003 have been fully considered but are not found persuasive. The examiner's rationale is set forth below.

15. Applicant argues that the "scope of the claims is clear" and thus the claim is definite (Response, pages 2-3). The examiner respectfully disagrees and maintains that it is unclear what would or would not comprise the above-cited members. Please note the following from MPEP 2173.02: If the scope of the invention sought to be patented cannot be determined from the language of the claims with a reasonable degree of certainty, a rejection of the claims under 35 U.S.C. 112, second paragraph is appropriate. *In re Wiggins*, 488 F.2d 538, 179 USPQ 421 (CCPA 1973).

16. Applicant also argues that the terms are "commonly used terms of art" and that one of ordinary skill "would be familiar with the common meaning and scope of these terms" (Response, page 3). The examiner respectfully disagrees. There is no specific art-known definition of what would constitute, e.g., "drugs" or "combinatorial compounds". Applicant is directed to MPEP 2173.05(a): [t]he meaning of every term used in a claim should be apparent from the prior art or from the specification and drawings at the time the application is filed. For these reasons, the rejection of claim 12 under 35 U.S.C. 112, second paragraph is maintained.

New Rejections – Necessitated by Amendment
Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1-5, 8-12 and 14-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Khrapko et al (US 5,552,270).

Khrapko et al disclose an array of oligonucleotides on a surface that comprises “a solid substrate and a matrix rigidly bound to the substrate” where the matrix “consists of a multiplicity of gel portions” (see Abstract, Figure 1 and column 2, lines 42-67). Glass substrates (slides) are disclosed by the reference, see column 3, line 64, reading on claim 3. These slides are treated with Triton X-100 (see, e.g. column 5, line 10), a polyethylene glycol derivative, reading on instant claims 4 and 5. As this element reads directly on the claims, the surface is assumed to inherently have the claimed “cytophobic” properties.

The solid substrate of Khrapko et al reads on the claimed “base” and the matrix is associated with the surface via non-covalent interactions (see column 3, line 63 – column 4, line 16), reading on claims 8 and 9. Note that the arrays of Khrapko et al are dried after formation (e.g. column 4, lines 6-8). The matrix (i.e. gel) used by Khrapko et al (see column 3, lines 61-62) reads directly on the “polymeric biomaterial elements” as claimed in instant claims 10 and 11. The reference discloses that oligonucleotides are contained in the gel portions, see e.g. column 5, lines 48-60, reading directly on claim 12.

The oligonucleotides can be non-covalently associated with the gel, see column 4, lines 8-16, reading on claim instant claim 14.

Finally, the size, density and arrangement of the elements (gel portions) of the array of Khrapko et al (reading on “polymeric biomaterial elements”) read directly on that claimed in the instant claims 15-20. See, for example, Figure 1 and patented claims 5 and 6 of the reference.

Status of Claims/Conclusion

19. No claims are allowed.
20. Applicant’s amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
May 2, 2003



MAURIE GARCIA BAKER PH.D
PRIMARY EXAMINER